UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: PLAVIX MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION (NO. II)	MDL No. 3:13-cv-02418-FLW-LHG
This Document Relates to: UNITED STATES OF AMERICA; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA, THE STATES OF CALIFORNIA, DELAWARE, CONNECTICUT, COLORADO, FLORIDA, GEORGIA, ILLINOIS, INDIANA, HAWAII, MICHIGAN, MONTANA, NEW MEXICO, NEW YORK, NEVADA, TENNESSEE, TEXAS, NEW JERSEY, RHODE ISLAND, OKLAHOMA, WISCONSIN, NORTH CAROLINA, AND MINNESOTA, THE CITY OF CHICAGO AND THE DISTRICT OF COLUMBIA *ex rel.* ELISA DICKSON, RELATOR, Plaintiffs, v. BRISTOL-MYERS SQUIBB COMPANY; SANOFI-AVENTIS U.S. LLC; SANOFI US SERVICES INC.; AND SANOFI-SYNTHELABO INC. Defendants.	Case No. 3:13-cv-01039-FLW-LHG **BRIEF IN SUPPORT OF MOTION FOR RECONSIDERATION OF THE TRANSFEROR COURT'S JANUARY 30, 2013 ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS** **Motion Day: April 1, 2013**

DEFENDANTS' BRIEF IN SUPPORT OF MOTION FOR RECONSIDERATION OF THE TRANSFEROR COURT'S JANUARY 30, 2013 ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

Defendants respectfully move, pursuant to Rule 7.1(i) of the Local Civil Rules of the United States District Court for the District of New Jersey and Rules 59(e) and 54(b) of the Federal Rules of Civil Procedure, to reconsider and amend two aspects of the Southern District of Illinois' January 30, 2013 Memorandum and Order ("Order") (Ex. A).[1] Specifically, we ask the Court to grant Defendants' motion to dismiss Relator's False Claims Act claims for Medicaid and Medicare Part D reimbursement. *See* Mem. of Law in Support of Defs.' Mot. to Dismiss Relator's Second Am. Compl. at 4-12 (Ex. B).

This Motion is necessary because Defendants did not have an opportunity to file a reply brief addressing fundamental legal errors in Relator's opposition to the motion to dismiss.[2] *See* Order, Ex. A at 12 n.8. Relator argued that Medicare imposed a "reasonable and necessary" standard as a precondition of payment, but failed to disclose that the "reasonable and necessary" test does not apply to important federal programs like Medicaid and Medicare Part D. *See*

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[1] In the Southern District of Illinois, the 28-day time limit in Federal Rule of Civil Procedure 59(e) applies to motions for reconsideration. The Southern District of Illinois docket in this case closed on February 14, 2013. A docket for this matter opened in this Court on February 21, 2013. Pursuant to the letter submitted to the Court by Defendants on February 19, 2013, the parties agreed that Defendants shall have three days from the date the docket in this case was opened to file this Motion for Reconsideration.

[2] Defendants do not seek reconsideration of the Court's Order regarding Medicare programs other than Medicare Part D. If Defendants had the opportunity to file a reply brief, however, Defendants would have pointed out that Medicare Parts A, B, and C do not even involve claims for Plavix® reimbursement, let alone false claims. Medicare Part A makes payments for hospital care based on the patients' diagnosis-related group code ("DRG") and age, not on the particular care, services, or prescription drugs that she receives. *See* 42 C.F.R. § 412.60(c)(2); *United States ex rel. Kennedy v. Aventis Pharm., Inc.*, No. 03 C 2750, 2008 WL 5211021, at *3 (N.D. Ill. Dec. 10, 2008). Medicare Part C payments, similarly, are not dependent on the drugs and/or services a patient receives. *See* 42 C.F.R. §§ 422.300 *et seq.*; *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 299 (3d Cir. 2011) (Part C Medicare Advantage plans paid "based on the number of patients enrolled in their Medicare programs"). Plavix® is not a drug reimbursed under Medicare Part B. *See* Ctr. for Medicare & Medicaid Servs., Medicare Part B Drug Average Sales Price, *available at*: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html?redirect= /mcrpartbdrugavgsalesprice/.

Relator's Opp'n to Defs.' Mot. to Dismiss ("Relator's Opp'n") at 3-4 (Ex. C). As a result, the Order incorrectly assumes the existence of a "reasonable and necessary" condition for payment for *all* federal programs in analyzing whether Defendants caused false claims to be presented to the federal government. *See Harsco Corp. v. Zlotnicki*, 779 F.2d 906, 909 (3d Cir. 1985) ("The purpose of a motion for reconsideration is to correct manifest errors of law or fact or to present newly discovered evidence."). The Court should grant reconsideration to correct that error.

ARGUMENT

Relator asserts a novel theory under the False Claims Act: that Defendants are liable for causing the government to pay for Plavix® prescriptions that doctors wrote for FDA-approved, "on-label" indications. But the "false certification" claims Relator asserts require an allegation that a defendant "knowingly falsely certifie[d] that it ha[d] complied with a statute or regulation the compliance with which is a condition for Government payment." *United States ex rel. Wilkins*, 659 F.3d at 305 (citation omitted). The Transferor Court found such an allegation of false certification based exclusively on a perceived requirement that all prescriptions must be "reasonable and necessary" as a "prerequisite to ***Medicare*** payment." Order, Ex. A at 4 (emphasis added). This was manifest error, because Medicaid and Medicare Part D -- the programs that reimbursed many of the claims at issue -- have no such "reasonable and necessary" standard for reimbursement.

Medicaid. The proper standard for prescription drug reimbursement under ***Medicaid*** is not whether the prescription was "reasonable and necessary." Relator tacitly conceded this by not citing a single statute, regulation, or source of authority to support a "reasonable and necessary" requirement. For a drug to be eligible for reimbursement under Medicaid, the manufacturer must enter a rebate agreement and the drug must be a "covered outpatient drug." 42 U.S.C. § 1396r–8(a)(1),(3); 42 U.S.C. § 1396b(i)(10). That is, drugs "approved for safety and

effectiveness" by FDA and prescribed for an FDA-approved use *must* be covered. 42 U.S.C. § 1396r–8(k)(2)(A)(i); 42 U.S.C. § 1396r–8(k)(6).

Under the Medicaid program, a state may establish a prior authorization requirement, 42 U.S.C. § 1396r-8(d)(1)(A), or refuse payment for a covered outpatient drug manufactured by a company with a Medicaid rebate agreement in only four circumstances, none of which apply here.[3] Here, Relator alleges only prescriptions for Plavix®'s FDA-approved indications. Thus, all prescriptions for Plavix® at issue necessarily are for a "covered outpatient drug" (Plavix® is approved by the FDA) and for a medically accepted indication.[4] Accordingly, these were proper Medicaid claims as a matter of law and the SAC does not and cannot allege they were "false." *See United States ex rel. Polansky v. Pfizer*, No. 04-0704-BMC, 2012 WL 5595933, at *6 (E.D.N.Y. Nov. 15, 2012) (dismissing FCA claims because defendant was not "doing anything 'false' or [] aiding in the submission of 'false claims' when it . . . is marketing the drug, after all, for an FDA sanctioned purpose").

Medicare Part D. Nor is "reasonable and necessary" a payment precondition for Medicare Part D coverage. Absent restrictions that Relator has not alleged, Medicare Part D plans must reimburse ***any*** "covered Part D drug," including drugs approved under the Federal

[3] The four circumstances are: (1) if the drug is not prescribed for a "medically accepted indication" (meaning FDA-approved indications and off-label uses supported by certain compendia); (2) if the drug is listed in § 1396r-8(d)(2) or is subsequently added to that list; (3) if an agreement between the state and the drug manufacturer restricts use of the drug; or (4) if the drug has been excluded by a state-established restrictive formulary. *See* 42 U.S.C. § 1396r-8(d)(1)(B). *See also In re Vioxx Prods. Liab. Litig.*, MDL No. 1657, 2010 WL 2649513, at *10-11 (E.D. La. June 29, 2010) (summarizing 42 U.S.C. § 1396r-8(2),(4)).

[4] *See* Second Amended Complaint ("SAC"), Ex. D ¶ 3 (conceding that this "action arises out of" promotion "for certain indicated usages"); Relator's Opp'n, Ex. C at 4 n.6 ("Relator's claims in no way challenge the FDA's approval of Plavix").

Food, Drug, and Cosmetic Act that are prescribed for an FDA-approved use. *See* 42 U.S.C. §1395w–102(e)(1); 42 U.S.C. § 1396r–8(k)(2)(A)(i); 42 U.S.C. § 1396r–8(k)(6).[5]

In holding that the "reasonable and necessary" standard is a "prerequisite to payment" under Medicare, the court relied entirely on authority pertinent only to Medicare Parts A and B. *See* Order, Ex. A at 4-5 (citing 42 U.S.C. § 1395y(a)(1)(A) ("[N]o payment may be made under ***part A or part B*** of this subchapter for any expenses incurred for items or services . . . [that] are not reasonable and necessary for the diagnosis or treatment . . . ."); *Mikes v. Straus*, 274 F.3d 687, 700-01 (2d Cir. 2001) (addressing alleged false claims for spirometry procedures reimbursed under Medicare Part B and predating the enactment of Medicare Part D); *Heckler v. Ringer*, 466 U.S. 602, 605 (1984) (addressing claims regarding "Part A of the Act"); *Almy v. Sebelius*, 679 F.3d 297, 299 (4th Cir. 2012) (addressing challenge to determination by Medicare Part B refusing to provide coverage for a medical device to treat osteoarthritis of the knee).[6] Because the SAC involves only prescriptions for FDA-approved uses of Plavix® (*see supra* note

[5] The Medicare statute provides that a Part D plan (or a Medicare Part C plan that offers Part D coverage called an MA-PD plan) "*may* exclude from qualified prescription drug coverage any covered part D drug . . . for which payment would not be made if [the "reasonable and necessary" standard in] section 1395y(a) of this title applied to [Part D]." 42 U.S.C. § 1395w-102(e)(3)(A) (emphasis added). But the decision to exclude a Part D drug from coverage in these circumstances is optional for the Part D or MA-PD plan, and the SAC fails to allege that any Plan has ever chosen to pursue this option and identifies no such Plan. Part D plans may also restrict coverage of drugs through formularies or other mechanisms under certain parameters and with approval of the Centers for Medicare and Medicaid Services ("CMS"). *See* 42 C.F.R. § 423.120; 42 C.F.R. § 423.272. Those restrictions are not at issue in this case.

[6] Furthermore, all of the cases cited by Relator in support of her argument addressed Medicare Part A or B. *See United Seniors Ass'n, Inc. v. Shalala*, 182 F.3d 965, 967 (D.C. Cir. 1999) ("Medicare Part B, which is the focus here, covers medical services including those provided by physicians."); *Mount Sinai Hosp. of Greater Miami Inc. v. Weinberger*, 517 F.2d 329, 334 (5th Cir. 1975) ("This case concerns [Medicare] Part A."); *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 346 (D. Conn. 2004) (addressing the standard for payment under Medicare Part A). Relator cites no source to refute the authority (including the statutes governing the programs) provided by Defendants regarding Part D and Medicaid.

4), and because Relator has not alleged any Part D plan restricted coverage of Plavix®, the prescriptions alleged were not false under Medicare Part D.[7]

CONCLUSION

Medicaid and Medicare Part D clearly require reimbursement for prescriptions for "on-label" uses of an FDA-approved drug. Because the SAC's allegations are limited to that exact type of prescription, the claims at issue are by definition not "false." Defendants respectfully ask the Court to grant reconsideration and to dismiss the SAC's claims related to Medicaid and Medicare Part D.

Respectfully submitted,

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[7] Relator does not allege that prescription reimbursements under CHAMPUS/TRICARE, CHAMPVA, and the Federal Employee Health Benefits Program ("FEHBP") impose a "reasonable and necessary" standard. Nor could she. CHAMPUS/TRICARE restricts prescription drug coverage only for "[u]nproven drugs, devices, and medical treatments or procedures," which the regulations define as "[a]ny drug, device, or medical treatment or procedure, the safety and efficacy of which have not been established." 32 C.F.R. § 199.4(g)(15). CHAMPVA provides reimbursement for any drug prescribed for a labeled indication provided that the drug is FDA approved for that indication, is prescribed by a "physician or other authorized professional provider," and is dispensed "in accordance with all applicable state laws and licensing requirements." *See* CHAMPVA Policy Manual, Ch. 2, Sec. 22.1, *available at*: http://www.va.gov/hac/forbeneficiaries/champva/policymanual/champva/chapter2/1c2s22-1.htm. There is no hint of a "reasonable and necessary" test in the statute governing FEHBP reimbursements. *See* 5 U.S.C. §§ 8901 *et seq.*

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